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06 September 2005

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Your Ref: 609728D1:SSI

Examiner's first report on patent application no. 2005200516
by American Medical Systems, Inc.

Last proposed amendment no.

Dear Madam/Sir,

I am replying to the request for normal examination. I have examined the application and I believe that there are lawful grounds of objection to the application. These grounds of objection are:

1. There is no Notice of Entitlement on file. You will need to file one because an application without a Notice of Entitlement cannot be accepted.

2. The specification does not comply with Section 40(4). The claims do not relate to one invention only (or to a group of inventions so linked as to form a single general inventive concept). In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be "special technical features". These are features that potentially distinguish the claimed combination of features from the prior art. Where different claims have different special technical features they define different inventions. I have found claims having different special technical features as follows:

   (1) Claims 1-14, 28, 29, 36-39 and 42 are related to a surgical kit, a needle converter and a procedure for treating incontinence using a sling wherein it is considered that having two types of needle which are different to each other comprises a first special technical feature.

   (2) Claims 15-19 and 30-35 are related to a surgical kit and procedure for treating incontinence using a sling wherein it is considered that having a first type of sling material and a second type of sling material comprises a second special technical feature.

   (3) Claims 20-23, 40 and 41 are related to method and device for treating incontinence in a female patient using a sling assembly for implantation without bone anchors wherein it is considered that having sutures associated with the sling assembly comprises a third special technical feature.

   (4) Claims 24-27 are related to an article for use in a surgical sling procedure wherein it is considered that the article comprising a body portion having first and second opposite end portions, the first end portion having surfaces for associating the article with a needle and the second end portion having a sling associator for associating the article with a sling comprises a fourth special technical feature.

(5) Claims 43-65 are related to a surgical kit or assembly of surgical items for treating female urinary incontinence wherein it is considered that having a first needle and a second guide needle comprises a fifth special technical feature.

(6) Claims 66 and 67 are related to a method of implanting a sling to treat urinary incontinence wherein it is considered that creating a pathway by initially passing a distal end of a needle through a suprapubic incision and then passing the distal end of the needle through a vaginal incision comprises a sixth special technical feature.

Since these groups of claims do not share any of the special technical features identified, a technical relationship between the inventions does not exist. Accordingly the claims do not relate to one invention or to a single inventive concept, a priori.

It is noted that claims 68-71 are appended to claims 65-67 and therefore may be grouped with either the fifth or sixth inventions.

I have limited the search and report to the invention defined by claims 1-14, 36-39, and 42. When I receive a response to my objections I may extend the search area and expand the report on the basis of my findings.

3. The invention defined in Claims 1-14, 28, 29, 36-39 and 42 does not involve an inventive step in light of the admitted prior art disclosed in paragraphs [0102]-[0109] and WO 1998/035616 A1 (BOSTON SCIENTIFIC IRELAND LIMITED, BARBADOS HEAD OFFICE) 20 August 1998.

   The claimed invention differs from the cited art in providing two types of needle which are different to each other rather than only one type of needle so as to afford the surgeon options that are unavailable in kits containing only one type of needle.

   I consider that this difference constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone.

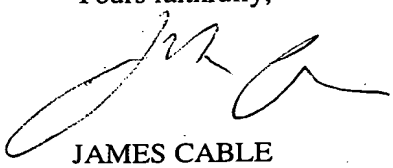
You have 21 months from the date of this report to overcome all my objection(s) otherwise your application will lapse.

You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

You will also need to pay any annual continuation fees that apply. These will normally be first due five years from the filing date. Please note however that earlier commencement dates apply for divisional applications.

Information about fees may be obtained by phoning 1300 651010.

Yours faithfully,



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The claims defining the invention are as follows:

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1. A surgical kit for treating incontinence comprising:

an implantable material suitable for a sling procedure,

at least one of a first type of needle suitable for a sling procedure, and

at least one of a second type of needle suitable for a sling procedure, wherein the first type of needle is different than the second type of needle.

2. A surgical kit according to claim 1 wherein the first type of needle comprises a substantially straight needle and the second type of needle comprises a needle with a curved portion.

3. A surgical kit according to claim 1 further including a synthetic insertion sheath associated with the implantable material to form a sling assembly.

4. A surgical kit according to claim 3 further including an adapter for associating the sling assembly with a surgical needle.

5. A surgical kit according to claim 4 wherein the adapter for associating the sling assembly with a surgical needle comprises a dilator.

6. A surgical kit according to claim 1 wherein the first type of needle comprises a needle with at least two handles.

7. A surgical kit according to claim 1 wherein the first type of needle includes an end portion with a passageway for receiving a suture.

8. A surgical kit according to claim 7 wherein the passageway for receiving a suture comprises a hole.

9. A surgical kit according to claim 1 wherein the first type of needle comprises a movable inner member with a blunt end portion having a suture passageway and an outer sheath member with a sheath end, and

means for moving the blunt end portion between i) an extended position with the suture passageway extending beyond the outer sheath member, and ii) a retracted position with the blunt end portion spaced closer to the end of the outer sheath member than in the extended position.

10. A surgical kit according to claim 9 wherein the sheath end comprises a substantially sharp surface for cutting tissue, and the first type of needle includes a means for locking the blunt end portion in the extended position.

11. A surgical kit according to claim 1 wherein the first type of needle includes at least two straight portions situated at a predetermined angle.

12. A surgical kit according to claim 1 further comprising a first type of handle and a second type of handle wherein the first type of handle is different than the second type of handle.

13. A surgical kit according to claim 1 wherein the first type of needle is larger than the second type of needle.

14. A surgical kit according to claim 1 wherein the first type of needle includes a bladder perforation detector.

15. A surgical kit for treating incontinence comprising:

a first type of sling material for implanting during a sling procedure,

a second type of sling material for implanting during a sling procedure,

at least one needle that is sized and shaped for inserting a sling material.

16. A surgical kit according to claim 15 wherein the first type of sling material is a synthetic sling material and the second type of sling material is a non-synthetic sling material.

17. A surgical kit according to claim 15 further including a universal adapter for associating a sling material with the needle.

18. A surgical kit according to claim 15 wherein the universal adapter comprises a compression collet.

19. A surgical kit according to claim 15 further including a means for constructing a sling from the first type of sling material and the second type of sling material.

20. A sling assembly for implantation without bone anchors, the sling assembly comprising:

a synthetic surgical mesh having first and second ends and a plurality of holes that are sized and shaped to afford tissue ingrowth, the synthetic surgical mesh being sized and shaped to be implanted during a surgical sling procedure,

a removable synthetic insertion sheath situated about the surgical mesh,

at least one suture operatively associated with the surgical mesh and extending beyond the first end of the surgical mesh a length sufficient to afford associating the mesh with a needle, and

at least one other suture operatively associated with the surgical mesh and extending beyond the second end of the surgical mesh a length sufficient to afford associating the mesh with a needle.

21. A sling assembly according to claim 20 wherein the insertion sheath defines an interior portion that includes the surgical mesh, and an exterior portion, and the suture extending beyond the first end of the surgical mesh extends from the interior portion of the sheath to an exterior portion of the sheath.

22. A sling assembly for implantation without bone anchors, the sling assembly comprising:

a synthetic surgical mesh having a plurality of holes that are sized and shaped to afford tissue ingrowth, the synthetic surgical mesh being sized and shaped to be implanted during a surgical sling procedure,

a removable synthetic insertion sheath situated about the surgical mesh and having first and second ends,

at least one suture operatively associated with the insertion sheath and extending beyond the first end of the insertion sheath a length sufficient to afford attachment of the sling assembly to a needle, and

at least one other suture operatively associated with the insertion sheath and extending beyond the second end of the insertion sheath a length sufficient to afford attachment of the sling assembly with a needle.

23. A sling assembly according to claim 22 wherein the insertion sheath defines an interior portion that includes the surgical mesh, and an exterior portion, and the sutures extending beyond the first and second ends of the insertion sheath are completely situated on the exterior portion of the sheath.

24. An article for use in a surgical sling procedure, the article comprising:

a body portion having first and second opposite end portions,

the first end portion having surfaces for associating the article with a needle, and

the second end portion having a sling associator for associating the article with a sling.

25. An article according to claim 24 wherein the sling associator comprises a hole.

26. An article according to claim 24 wherein the sling associator includes a slot for receiving a first or a second type of sling or sling assembly and a securement means for securing the first or the second type of sling or sling assembly to the article.

27. An article according to claim 24, wherein the sling associator comprises jaws movable from an open position for receiving a sling material to a closed position that firmly retains the sling and that resists separation of the sling from the article.

28. A surgical kit assembly comprising:

a sling assembly comprising a sling mesh material and an adapter, the adapter having an end portion having a passageway,

a first type of needle having first and second end portions, at least one of the end portions being sized and shaped to engage complementary surfaces in the passageway of the end portion of the adapter to associate the needle with the sling assembly, and

a needle converter having a first end portion having surfaces that are sized and shaped to engage complementary surfaces in the passageway of the adapter to associate the needle converter with the adapter, the needle converter having a second end portion, opposite the first

end portion, which second end portion has a means for attaching the needle converter to a second type of needle that is different than the first type of needle.

29. A needle converter for use in a surgical sling procedure that utilizes a dilator for use with a first type of needle, the needle converter comprising:

a body portion,

a first end portion having surfaces that are sized and shaped to engage complementary surfaces in a passageway of a dilator to associate the needle converter with the dilator,

second end portion, opposite the first end portion, which second end portion has a means for attaching the needle converter to a second type of needle that is different than the first type of needle.

30. A surgical kit assembly comprising:

a first type of sling material for implanting during a sling procedure,

at least one needle that is sized and shaped for inserting a sling material, and

sling assembly means for affording construction of a customized sling from the first type of sling material and a second type of sling material.

31. A surgical kit according to claim 30 wherein the sling assembly means comprises a grommet constructed from a biocompatible material.

32. A surgical sling procedure comprising the steps of:

providing a kit comprising a first type of sling material for implanting during a sling procedure, and a sling assembly means for affording construction of a sling from the first type of sling material and a second type of sling material,

constructing a sling by selecting at least a portion of the first type of sling material and a second type of sling material and by associating the selected first type of sling material with the second type of sling material, and

implanting the constructed sling.

33. A surgical sling procedure according to claim 32 wherein the step of providing a sling assembly means comprises the step of providing a mechanical fastener to attach the first type of sling material to the second type of sling material.

34. A surgical sling procedure for treating incontinence comprising the steps of:

providing a surgical kit having a first type of sling material for implanting during a sling procedure, a second type of sling material for implanting during a sling procedure, and a surgical instrument for implanting a sling material,

selecting the first type of sling material or the second type of sling material from the surgical kit, and

implanting the selected sling material with the surgical instrument.

35. A surgical procedure according to claim 34 where in the step of providing a first type of sling material comprises providing a first type of polymeric sling material, and the step of providing a second type of sling material comprises the step of providing a second type of polymeric sling material that is different than the first type of polymeric sling material.

36. A surgical sling procedure for treating incontinence comprising the steps of:

providing a surgical kit with an implantable material suitable for a sling procedure, at least one of a first type of needle that is sized and shaped for inserting a sling, and at least one of a second type of needle that is sized and shaped for inserting a sling, wherein the first type of needle is different than the second type of needle,

selecting the first or the second type of needle, and

implanting the implantable material using the selected needle.

37. A method of implanting a sling to treat urinary incontinence in a patient comprising the steps of:

providing a surgical kit comprising at least one guide needle, and at least one sling transport needle with a tip, a sling attached to the sling transport needle, and an adapter having tip receiving surfaces for receiving the tip of the sling transport needle,

creating at least one vaginal incision,

creating at least one suprapubic incision,

initially passing the guide needle through the suprapubic incision and then through the vaginal incision,

attaching the adapter to the needle,

placing the tip of the sling transport needle in the tip receiving surfaces of the adapter, and

guiding the sling transport needle from the vaginal incision to the suprapubic incision with the guide needle to implant the sling.

38. A surgical kit for treating incontinence comprising:

at least one guide needle,

at least one sling transport needle with a tip, and a sling attached to the sling transport needle, and

an adapter having tip receiving surfaces for receiving the tip of the sling transport needle and having means for attaching to the at least one guide needle.

39. A surgical kit according to claim 38 wherein the adapter is integral with the guide needle.

40. A method of treating incontinence in a female patient comprising the steps of:

providing a synthetic surgical mesh having first and second ends and a plurality of holes that are sized and shaped to afford tissue ingrowth, and a removable synthetic insertion sheath situated about the surgical mesh,

extending a first suture through the surgical mesh and beyond the first end of the surgical mesh,

extending a second suture through the surgical mesh and extending beyond the second end of the surgical mesh,

creating at least one vaginal incision,

creating at least one suprapubic incision,

passing a leading end of a needle initially through a suprapubic incision and then through the vaginal incision on one side of the patient's urethra,

passing a leading end of a needle initially through a suprapubic incision and then through the vaginal incision on the other side of the patient's urethra,

attaching the first suture to the leading end of a needle on one side of the patient's urethra,

attaching the second suture to the leading end of a needle on the other side of the patient's urethra,

implanting the sling by moving the leading end of a needle from the vaginal incision toward a suprapubic incision, and

then removing the synthetic insertion sheath.

41. A method of treating incontinence in a female patient comprising the steps of:

providing a synthetic surgical mesh having a plurality of holes that are sized and shaped to afford tissue ingrowth, a removable synthetic insertion sheath situated about the surgical mesh and having first and second ends,

associating a first suture with the insertion sheath and extending the first suture beyond the first end of the insertion sheath,

associated a second suture with the insertion sheath and extending the second suture beyond the second end of the insertion sheath,

creating at least one vaginal incision,

creating at least one suprapubic incision,

passing a leading end of a needle initially through a suprapubic incision and then through the vaginal incision on one side of the patient's urethra,

passing a leading end of a needle initially through a suprapubic incision and then through the vaginal incision on the other side of the patient's urethra,

attaching the first suture to a leading end of a needle on one side of the patient's urethra,

attaching the second suture to the leading end of a needle on the other side of the patient's urethra,

implanting the sling by moving the leading end of a needle from the vaginal incision toward a suprapubic incision,

cutting end portions of the sling mesh and synthetic insertion sheath to separate them from portions implanted in the patient, and

removing a remaining portion of the synthetic insertion sheath from the surgical mesh.

42. A surgical kit for treating incontinence comprising:

an implantable material suitable for a sling procedure,

a needle that is sized and shaped for inserting a sling, the needle having surfaces for engaging a handle, and

at least one of a first type of handle having surfaces for attaching the handle to the needle, and

at least one of a second type of handle having surfaces for attaching the handle to the needle, wherein the first type of needle is different than the second type of needle.

43. An assembly of surgical articles for treating female urinary stress incontinence comprising:

a mesh for implanting to support the patient's urethra

a first curved needle with a curved shaft, a distal end portion and a proximal end portion, the proximal end portion being attached to the mesh;

a second curved guide needle having a proximal end portion and a distal end portion;

a handle for the proximal end portion of the second curved guide needle; and

a connector for association between the distal end portion of the first needle and the distal end portion of the second curved guide needle.

44. An assembly of surgical articles according to claim 43 wherein the second guide needle has a diameter of less than 4 mm.

45. An assembly of surgical articles according to claim 43 or claim 44 wherein the distal end portion of the first curved needle includes a sharp tip.

46. An assembly of surgical articles according to any one of claims 43 to 45 wherein the connector has leading end portion that is tapered for expanding tissue already traversed by the second guide needle, and a trailing end.

47. An assembly of surgical articles according to claim 46 wherein the connector has an internal passageway from the leading end portion to the trailing end, a portion of the internal passageway near the leading end portion adapted to receive the distal end portion of the second curved guide needle, and a portion of the internal passageway near the trailing end adapted to receive the distal end portion of the first curved needle.

48. An assembly of surgical articles according to any one of claims 43 to 47 wherein the mesh comprises a knitted polypropylene mesh.

49. An assembly according to any one of claims 43 to 48 wherein the mesh has between 25.5 and 29.5 courses/inch and between 11 and 15 wales/inch.

50. An assembly of surgical articles according to any one of claims 43 to 49 wherein the connector includes complementary engagement surfaces for securely attaching the first curved needle tot he second curved needle.

51. An assembly of surgical articles according to any one of claims 43 to 50 wherein the first curved needle, the second curved guide needle and the connector have an axial length, and the length of the connector is less than the length of the first curved needle and the second curved guide needle.

52. An assembly of surgical articles according to any one of claims 43 to 51 further including a polyethylene insertion sheath about the mesh comprising two elongate, separable sections.

53. An assembly of surgical articles according to claim 51 wherein the connector has an overall length of less than 2.5 inches (63.5 mm).

54. An assembly of surgical articles according to any one of claims 43 to 53 wherein the handle for the proximal end portion of the second curved guide needle is non-removable.

55. An assembly of surgical articles according to claim 54 wherein the handle includes finger indents.

56. An assembly according to any one of claims 43 to 55 further including a handle adapted to be connected to the proximal end portion of the first curved needle.

57. an assembly according to any one of claims 43 to 56 wherein the connector comprises a polymeric material.

58. An assembly of surgical articles according to claim 51 wherein the second curved guide needle is constructed from a malleable material.

59. An assembly of surgical articles according to claim 58 wherein the malleable material is a stainless steel.

60. An assembly of surgical articles for treating female urinary stress incontinence comprising:

a mesh for implanting to support the patient's urethra

a first curved needle with a curved shaft, a distal end portion and a proximal end portion, the proximal end portion being attached to the mesh;

a second curved guide needle having a proximal end portion and a distal end portion;

a handle for the proximal end portion of the second curved guide needle; and

a connector for association between the distal end portion of the first needle and the distal end portion of the second curved guide needle, substantially as hereinbefore described with reference to the drawings.

61. An assembly of surgical articles for treating female urinary stress incontinence comprising:

a mesh for implanting to support the patient's urethra

a first curved needle with a curved shaft, a distal end portion and a proximal end portion, the proximal end portion being attached to the mesh;

a second curved guide needle having a proximal end portion and a distal end portion;

a handle for the proximal end portion of the second curved guide needle; and

a connector for association between the distal end portion of the first needle and the distal end portion of the second curved guide needle, substantially as hereinbefore described with reference to the Examples.

62. A surgical kit for treating incontinence comprising:

at least one guide needle with a handle,

at least one sling transport needle with a tip, and a sling attached to the sling transport needle, and

an adapter having tip receiving surfaces for receiving the tip of the sling transport needle and having means for associating with at least one guide needle.

63. A surgical kit according to claim 60 wherein the handle has finger indents.

64. A surgical kit of surgical articles for treating female urinary stress incontinence comprising:

a mesh for implanting to support the patient's urethra

a first curved needle with a curved shaft, a distal end portion and a proximal end portion, the proximal end portion being attached to the mesh;

a second curved guide needle having a proximal end portion and a distal end portion;

a handle for the proximal end portion of the second curved guide needle; and

a connector for association between the distal end portion of the first needle and the distal end portion of the second curved guide needle, substantially as hereinbefore described with reference to the drawings.

65. A surgical kit of surgical articles for treating female urinary stress incontinence comprising:

a mesh for implanting to support the patient's urethra

a first curved needle with a curved shaft, a distal end portion and a proximal end portion, the proximal end portion being attached to the mesh;

a second curved guide needle having a proximal end portion and a distal end portion;

a handle for the proximal end portion of the second curved guide needle; and

a connector for association between the distal end portion of the first needle and the distal end portion of the second curved guide needle, substantially as hereinbefore described with reference to the Examples.

66. A method of implanting a sling to treat urinary incontinence in a female patient comprising the steps of:

creating at least one incision in vaginal tissue,

creating at least one suprapubic incision,

providing first and second guide needles that are sized, shaped and designed to be initially passed from a suprapubic incision toward a vaginal incision, the guide needles each having distal ends, and handles,

creating a first pathway by initially passing the distal end of the first needle through a suprapubic incision and then passing the distal end of the first needle through a vaginal incision,

creating a second pathway by initially passing the distal end of the second needle though a suprapubic incision and then passing the distal end of the second needle through a vaginal incision,

providing first and second connectors and a synthetic implantable material,

connecting one of the connectors to the distal end of the first needle after the first needle emerges from a vaginal incision,

connecting the other connector to the distal end of the second needle after the second needle emerges from a vaginal incision, and

moving the distal ends of the first and second needles and the connectors from a vaginal incision toward a suprapubic incision to implant the implantable material in a therapeutically effective position.

67. A method according to claim 66 wherein the step of creating a first pathway by initially passing the distal end of the first needle through a suprapubic incision and then passing the distal end of the second needle through a vaginal incision includes the step of:

identifying the posterior portion of the patient's pubic bone with the distal end of the second needle to controllably move the distal end of the second needle toward the vaginal incision and to avoid damaging structures such as the urethra and bladder of the patient.

68. A method according to any one of claims 65 to 67 wherein the step of moving the distal ends of the first and second needles and the connectors from a vaginal incision toward a suprapubic incision to implant the implantable material in a therapeutically effective position includes the step of:

implanting the material mid-urethra.

69. A method according to any of claims 65 to 67 wherein the step of providing a connector includes the step of providing a connector with a taper on a leading edge thereof, and

the step of moving the distal ends of the first and second needles and the connectors from a vaginal incision toward a suprapubic incision includes the step of expanding the first and second pathways provided by the first and second needles with the tapered surfaces of the connectors.

70. A method according to any one of claims 65 to 69 wherein the step of providing first and second connectors and a synthetic implantable material includes the step of:

providing a protective sheath situated about the implantable material, the sheath being constructed of a material that affords visual examination of the implantable material and that affords passage of the sling assembly through tissue of a patient, and

the method includes the step of removing the protective sheath from the patient and leaving the implantable material.

71. A method according to any one of claims 65 to 70, further including the step of verifying the absence of a bladder perforation via cystoscopy after creation of the first pathway but prior to connecting a connector to the distal end of the first needle.

Dated 7 February, 2005

American Medical Systems, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON